

**Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine (DTaP)
Hepatitis B Vaccine, Recombinant (HepB)
Inactivated Poliomyelitis Vaccine (EIPV)**

Manufacturer	GlaxoSmithKline
Brand Name	PEDIARIX
Formulation	5 one-dose vials Single dose Tip-Lok syringe (no needle)
Dosage	0.5 ml
Storage	Refrigerate immediately. Store at 2°-8° C (35°-46° F). Do not freeze.
Injection Site	Anterolateral aspect of the upper thigh or deltoid
Route	Intramuscular (IM)
Needle Size	22 to 25 gauge, 7/8 to 1¼ inches
Administration	May be administered simultaneously or at any interval between doses of inactivated or live antigen.

Routine DTaP/HepB/EIPV Combination schedule for vaccination of children:

Dose	Customary Age	Minimum Interval
1	2 months	6 weeks or older
2	4 months	4 weeks after first dose
3	6 months	8 weeks after second dose

1. PEDIARIX is interchangeable with all US-licensed **EIPV** and **HepB** vaccines
2. PEDIARIX is indicated to complete the first 3 doses of the primary series in infants who started the series with *Infanrix*.
3. Because the pertussis antigen components of PEDIARIX are the same as those in INFANRIX, these children should receive INFANRIX as their fourth and fifth dose of DTaP.
4. **However, if previously administered DTaP vaccine cannot be determined or is not available, any licensed DTaP vaccine may used to complete the series.** No efficacy or safety data is available for this schedule.
5. A birth dose of monovalent hepatitis B vaccine remains a part of the infant immunization schedule when PEDIARIX is used. Although not labeled for this indication by FDA, PEDIARIX may be used in infants whose mothers are HBsAg positive or whose HBsAg status is not known.
6. Children who have received a 3-dose primary series of PEDIARIX should receive a fourth dose of EIPV at 4 to 6 years of age.
7. PEDIARIX may be administered at 2, 4, and 6 months to infants who received a birth dose of hepatitis B vaccine (total of 4 doses of hepatitis B vaccine)

Contraindications to DTaP/HepB/EIPV Combination vaccination:

1. Moderate to severe illness (i.e. child appears ill)
2. Anaphylactic reaction following a prior dose of vaccine
3. Hypersensitivity to yeast, neomycin or polymyxin B
4. Encephalopathy, not due to another cause, occurring within 7 days following a DTP/DTaP vaccination.

Precautions to DTaP/HepB/EIPV Combination vaccination:

1. Fever equal to or greater than 40.5° C (105° F) within 48 hours of previous DTP/DTaP vaccination not due to another identifiable cause.
2. Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of previous DTP/DTaP vaccination.
3. Persistent, inconsolable crying lasting more than 3 hours, occurring within 48 hours of previous DTP/DTaP vaccination.
4. Convulsions with or without fever occurring within 3 days of previous DTP/DTaP vaccination.
5. Progressive or evolving neurologic disorder.